

IPR

ARNOLD & PORTER LLP



Milan M. Vinnola

Milan_Vinnola@aporter.com

202.942.6111

202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

July 1, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Art Unit: 1614
Conf. No.: 5134

Re: U.S. Patent Application Serial No. 10/741,534 filed December 19, 2003
Inventors: Alain BARON *et al.*
Title: Compositions for the Treatment and Prevention of Nephropathy
Atty. Dkt: 18528.675 / 0218-UTL-9

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Information Disclosure Statement;
2. Form PTO/SB08a (2 pages) and Form PTO/SB08b (2 pages), with 25 accompanying documents; and
3. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 18528.675. A duplicate copy of this letter is enclosed.

Sincerely,

Milan M. Vinnola (Reg. No. 45,979)

Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Alain BARON *et al.*

Appl. No.: 10/741,534

Filed: December 19, 2003

For: Compositions for the Treatment and Prevention of Nephropathy

Confirmation no.: 5134

Art Unit: 1614

Examiner: To Be Assigned

Atty. Docket: 18528.675 / 0218-UTL-9

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Forms PTO-SB08a and PTO-SB08b. It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

However, Applicants make no representation or admission regarding the relevance or availability of the cited references as "prior art" to the present application.

CERTIFICATION AND/OR FEE

Because this Information Disclosure Statement is being submitted prior to the mailing date of the first action on the merits in the above-captioned application, it is believed that no fee is required. However, if it is deemed that a fee is required for submission of this Information Disclosure Statement and consideration of the attached documents, authorization is given in the accompanying transmittal letter.

Respectfully submitted,

Thomas E. Holsten (Reg. No. 46,098)
Milan M. Vinnola (Reg. No. 45,979)

Date: July 1, 2004

ARNOLD & PORTER LLP
Attn: IP Docketing
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

4

Complete if Known

Application Number	10/741,534
Filing Date	December 19, 2003
First Named Inventor	Alain BARON
Art Unit	1614
Examiner Name	To Be Assigned

Attorney Docket Number 18528.675

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A1	US-	2002/0137666 A1	09-26-2002	Beeley <i>et al.</i>	
B1	US-	2003/0087820 A1	05-08-2003	Young <i>et al.</i>	
C1	US-	2003/0220243 A1	11-27-2003	Glaesner <i>et al.</i>	
D1	US-	5,118,666	06-02-1992	Habener	
E1	US-	5,120,712	06-09-1992	Habener	
F1	US-	5,512,549	04-30-1996	Chen <i>et al.</i>	
G1	US-	5,545,618	08-13-1996	Buckley <i>et al.</i>	
H1	US-	5,574,008	11-12-1996	Johnson <i>et al.</i>	
I1	US-	5,670,360	09-23-1997	Thorens	
J1	US-	5,705,483	01-06-1998	Galloway <i>et al.</i>	
K1	US-	5,846,747	12-08-1998	Thorens <i>et al.</i>	
L1	US-	5,981,488	11-9-1999	Hoffmann	
M1	US-	6,051,689	04-18-2000	Thorens	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
N1		EP 0 708 179 A2	04-24-1996	Eli Lilly and Company		
O1		WO 91/11457 A1	08-08-1991	Douglas I. BUCKLEY <i>et al.</i>		
P1		WO 98/05351 A1	02-12-1998	Amylin Pharmaceuticals, Inc.		
Q1		WO 98/30231 A1	07-16-1998	Amylin Pharmaceuticals, Inc.		
R1		WO 99/07404 A1	02-18-1999	Amylin Pharmaceuticals, Inc.		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

JUL 01 2004

PATENT & TRADEMARK OFFICE

C25

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/741,534
Filing Date	December 19, 2003
First Named Inventor	Alain BARON
Art Unit	1614
Examiner Name	To Be Assigned

Sheet

2

of

4

Attorney Docket Number

18528.675

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A2	US-	6,268,343 B1	07-31-2001	Knudsen <i>et al.</i>	
B2	US-	6,451,974 B1	09-17-2002	Hansen	
C2	US-	6,451,987 B1	09-17-2002	Staby	
D2	US-	6,458,924 B2	10-01-2002	Knudsen <i>et al.</i>	
E2	US-	6,514,500 B1	02-04-2003	Bridon <i>et al.</i>	
F2	US-	6,528,486 B1	03-04-2003	Larsen <i>et al.</i>	
G2	US-	6,569,832 B1	05-27-2003	Knudsen <i>et al.</i>	
H2	US-	6,593,295 B2	07-15-2003	Bridon <i>et al.</i>	
I2	US-				
J2	US-				
K2	US-				
L2	US-				
M2	US-				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
N2		WO 99/25727 A2	05-27-1999	Amylin Pharmaceuticals, Inc.		
O2		WO 99/25728 A1	05-27-1999	Amylin Pharmaceuticals, Inc.		
P2		WO 01/98331 A2	12-27-2001	Eli Lilly and Company		
Q2		WO 02/48192 A2	06-20-2002	Eli Lilly and Company		
R2						

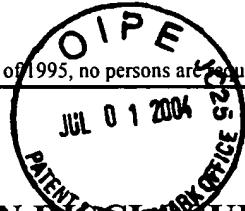
Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

Application Number	10/741,534
Filing Date	December 19, 2003
First Named Inventor	Alain BARON
Art Unit	1614
Examiner Name	To Be Assigned

Attorney Docket Number 18528.675

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A3	Adelhorst <i>et al.</i> , "Structure-Activity Studies of Glucagon-Like Peptide-1," <i>J. Biol. Chem.</i> , 269(9):6275-6278 (1994)	
	B3	Byrne <i>et al.</i> , "Human Studies with Glucagon-Like-Peptide-1: Potential of the Gut Hormone for Clinical Use," <i>Diabet. Med.</i> , 13(10):854-860 (1996) (Abstract)	
	C3	D'Alessio <i>et al.</i> , "Elimination of the Action of Glucagon-Like Peptide 1 Causes and Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," <i>J. Clin. Invest.</i> , 97(1):133-138 (1996)	
	D3	Eng <i>et al.</i> , "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <i>J. Biol. Chem.</i> , 265(33):20259-20262 (1990)	
	E3	Eng <i>et al.</i> , "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," <i>J. Biol. Chem.</i> , 267(11):7402-7405 (1992)	
	F3	Hjorth <i>et al.</i> , "Glucagon and Glucagon-Like Peptide 1: Selective Receptor Recognition via Distinct Peptide Epitopes," <i>J. Biol. Chem.</i> , 269(48):30121-30124 (1994)	
	G3	Holz <i>et al.</i> , "Black Widow Spider Alpha-Latrotoxin: A Presynaptic Neurotoxin that Shares Structural Homology with the Glucagon-Like Peptide-1 Family of Insulin Secretagogic Hormones," <i>Comp. Biochem. Biophysiol.</i> , 121(2):177-184 (1998) (Abstract)	
	H3	Irwin <i>et al.</i> , "The <i>Xenopus</i> Proglucagon Gene Encodes Novel GLP-1-Like Peptides with Insulinotropic Properties," <i>Proc. Natl. Acad. Sci. USA</i> , 94:7915-7920 (1997)	
	I3	Mojsov, "Structural Requirements for Biological Activity of Glucagon-Like Peptide-I," <i>Int. J. Pept. Protein Res.</i> , 40(3-4):333-343 (1992) (Abstract)	
	J3	O'Halloran <i>et al.</i> , "Glucagon-Like Peptide-1 (7-36)-NH ₂ : A Physiological Inhibitor of Gastric Acid Secretion in Man," <i>J. Endocrinol.</i> , 126(1):169-173 (1990) (Abstract)	
	K3	Orskov <i>et al.</i> , "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects are Indistinguishable," <i>Diabetes</i> , 42(5):658-661 (1993) (Abstract)	

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

JUL 01 2004

U.S. PATENT AND TRADEMARK OFFICE
C25INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

4

of

4

Complete if Known

Application Number	10/741,534
Filing Date	December 19, 2003
First Named Inventor	Alain BARON
Art Unit	1614
Examiner Name	To Be Assigned

Attorney Docket Number 18528.675

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A4	Raufman <i>et al.</i> , "Truncated Glucagon-Like Peptide-1 Interacts with Exendin Receptors on Dispersed Acini from Guinea Pig Pancreas," <i>J. Biol. Chem.</i> , 267(30):21432-21437 (1992)	
	B4	Ritzel <i>et al.</i> , "A Synthetic Glucagon-Like Peptide-1 Analog with Improved Plasma Stability," <i>J. Endocrinol.</i> , 159:93-102 (1998)	
	C4	Schjoldager <i>et al.</i> , "GLP-1 (Glucagon-Like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," <i>Dig. Dis. Sci.</i> , 34(5):703-708 (1989) (Abstract)	
	D4	Wettergren <i>et al.</i> , "Truncated GLP-1 (Proglucagon 78-107-amide) Inhibits Gastric and Pancreatic Functions in Man," <i>Dig. Dis. Sci.</i> , 38(4):665-673 (1993) (Abstract)	
	E4	Willms <i>et al.</i> , "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," <i>J. Clin. Endocrinol. Metab.</i> , 81(1):327-332 (1996) (Abstract)	
	F4		
	G4		
	H4		
	I4		
	J4		
	K4		

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.